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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,558

06/17/2005

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06/22/2010

EXAMINER

KOSAR, ANDREW D

ART UNIT

PAPER NUMBER

1654

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/539,558	<b>Applicant(s)</b> HILLMAN, YITZCHAK	
	<b>Examiner</b> ANDREW D. KOSAR	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 100-108 and 113-126 is/are pending in the application.
- 4a) Of the above claim(s) 100-108 and 117-122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 113-116 and 123-125 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendments/Arguments***

Applicant's amendments and arguments filed March 15, 2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

Applicant is reminded that all amendments must properly indicate cancelled subject matter via ~~strike through~~ and added subject matter by underline. Additionally, Applicant should be aware that Applicant cannot withdraw claims from consideration in response to negative findings by the Office, e.g. a rejection against the claim. Proper replies will traverse the rejection and/or amend the claim, or cancel the claim. In order to advance prosecution, the amendment has been accepted as compliant. Future replies not in compliance with the rules and regulations will not be afforded such consideration.

Applicant has added new claim 126, dependent upon withdrawn claim 118. Claims 100-108 and 118-121 and new claim 126 are/remain withdrawn for the reasons of record. Applicant has amended claim 122 to read upon psoriasis. Similarly, claim 117 has been amended to only be a GI disease, however the art previously applied does not read upon that element. Because the art of record is still applicable to the claims, as set forth below, the search has not been extended to cover psoriasis or GI diseases. Thus, claims 117 and 122 are withdrawn from consideration. Claims 113-116 and 123-125 have been examined on the merits.

Applicant has argued the amendments overcome the rejections of record, however Gallo teaches treating a skin condition - psoriasis- with LL-37, and Hancock teaches treating arthritis with antimicrobial peptides. In light of the teachings of Hancock, it is obvious to combine the

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two references to arrive at the method of treating arthritis with LL-37. As for the double patenting rejection, Applicant has indicated they would reply upon securing patent legal counsel. The rejection is maintained for the reasons of record.

New rejections are presented in light of the claim amendments, as new issues of indefiniteness are resultant from the amendments presented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 123** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 123 lacks clear antecedent basis, in that it depends from claim 122, however claim 122 is drawn to the disease being psoriasis, and arthritis is not a species of psoriasis.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 113-116, 124 and 125** are rejected under 35 U.S.C. 102(e) as being anticipated by GALLO (US 2006/0292551 A1).

Gallo teaches treating atopic dermatitis with cationic antiviral peptides (e.g. claim 20), such as LL-37 (e.g. claim 21, identified as SEQ ID NO:1).

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It should be noted that Gallo is properly applied as prior art, as the instant foreign priority document filed in Israel (153557) on December 19, 2002 fails to provide support for the subject matter claimed. 153557 provides for treating/preventing diseases (e.g. claim 1 and 16), including dermatitis (e.g. claim 16) with blocking agents of antimicrobial peptides (e.g. claim 4). The context of the priority document is such that inhibition of the AMPs/AMLs is how one treats diseases such as dermatitis. The document does not provide, within the meaning of 35 USC 112, 1<sup>st</sup> ¶, descriptive support for the now-claimed subject matter. Further, foreign priority document 156980 provides the same teachings that blocking agents are necessary to treat such diseases (e.g. claims 1, 3, 4, 20 and page 13 "In this patent, antagonists or blockers for antimicrobial peptides includes blockers or antagonists for all or any one combination of all antimicrobial peptides including the following:..."). Further, 156980 provides that diseases such as dermatitis are triggered by AMPs (e.g. page 15).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 123** is rejected under 35 U.S.C. 103(a) as being unpatentable over HANCOCK, (US Patent 6,288,212 B1), in view of GALLO, above.

It is noted that claim 123 does not properly depend from claim 122, which has been withdrawn from consideration. The rejection is set forth only for claim 123 as if it were an independent claim.

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The teachings of Hancock and Gallo are presented above and previously. While Hancock teaches treating various conditions, including arthritis, with antimicrobial peptides (e.g. column 14, lines 42-67), Hancock does not teach using LL-37. It would have been obvious to have used LL-37 in the methods of Hancock, as Hancock teaches that any antimicrobial peptide can be used in the method. One would have been motivated to have used any antimicrobial peptide, including LL-37, as Hancock teaches any antimicrobial peptide can be used. One would reasonably expect LL-37 to work in the method, as it is within the genus of antimicrobial peptides disclosed by Hancock that are taught to be effect for the treatments disclosed therein.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the foregoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 113-116 and 123-125** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 12/173,344.

Although the conflicting claims are not identical, they are not patentably distinct from each other. In the instant case, '344 is a CIP of the instant case and embraces/claims methods of overlapping, if not commensurate, scope, such that the methods of '344 anticipate the instant claims. For example, '344 is drawn to treating medical conditions, e.g. arthritis (claim 7) with antimicrobial peptides, e.g. LL-37 (e.g. claim 4). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW D. KOSAR whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 08:00 - 16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew D Kosar/

Primary Examiner, Art Unit 1654